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Case Report

Essure Surgical Removal and Subsequent Symptom Resolution: Case Series and Follow-Up Survey

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ABSTRACT Transcervical sterilization is a minimally invasive option for permanent contraception with high reported rates of patient satisfaction. A small percentage of women subsequently choose to have the tubal inserts removed due to regret or perceived side effects. There is limited information with regard to the improvement in the symptom profile following surgical removal of the tubal inserts. We present a retrospective case series of 11 women who underwent surgical removal of Essure by hysteroscopy, salpingectomy, and/or hysterectomy. The predominant symptom at presentation was pain (n = 10; 90.91%), as well as bleeding (n = 6; 54.54%) and/or dyspareunia (n = 5; 45.45%). After surgical removal, the majority of patients (n = 8; 72.72%) reported an improvement of their symptoms. However, 3 (27.27%) patients continued to have persistent symptoms after surgery. Before surgical removal of Essure, it is important to thoroughly discuss the risk of continuing symptoms with patients. Journal of Minimally Invasive Gynecology (2015) 22, 910–913 © 2015 AAGL. All rights reserved.

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Essure (Bayer AG, Leverkusen, Germany) is a sterilization device that consists of an expanding micro-insert that is inserted into the cornual section of the fallopian tube during hysteroscopy [1]. The initial 5-year placement success rates by tubal occlusion ranged from 84% to 99.8% [2]. The US Food and Drug Administration approved its use in the United States in 2002.

One important risk of the procedure is the chance of regret, which is reported to be as high as 5.5% [3]. Some patients present after Essure placement, requesting removal of these devices because of complaints of pain, identification of a misplaced insert, the desire for fertility, or a presumed allergic reaction. The removal can be classified into 2 broad categories: hysteroscopic removal (typically preferred for the patients who had the device inserted <12 weeks) and laparoscopic extraction (in patients whose devices are outside the window for hysteroscopic removal or if the insert has perforated the abdominal cavity) [4].

There is scant literature regarding outcomes of women who undergo Essure implant removal. Therefore, the primary objective of this study was to survey women regarding symptom resolution following removal of Essure devices.

Methods

This retrospective case series included women who sought surgical management for the removal of Essure between September 2012 and July 2014 at the Division of Minimally Invasive Gynecologic Surgery at Brigham and Women's Hospital in Boston, MA. The project was approved by the Partners Institutional Review Board. Women who underwent Essure removal due to desire for future pregnancy or sterilization regret were excluded.

The following demographic characteristic data were abstracted from the medical record: age, race, body mass index (BMI), parity, comorbidities, clinical symptoms after Essure placement, duration of symptoms, type of surgery,

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Table 1

Patient baseline characteristics

Patient no.	Age (yrs)	Race	Parity	BMI (kg/m^2)	Comorbidities	Duration of symptoms[a]
1	35	White	3	24.7	Asthma, chronic low back pain	5
2	44	White	3	35	Migraine, chronic low back pain	9
3	28	Declined	2	24.7	Constipation, chronic low back pain	7
4	35	White	7	19.7	Chronic low back pain	2
5	41	White	2	26.6	Chronic headache	5
6	42	White	5	32.8	Diabetes, hypertension, depression	2
7	44	White	2	21.5	Constipation, chronic low back pain, asthma	2
8	25	White	2	21.3	None	1
9	30	White	4	25.3	None	0.5
10	34	Black	4	21.6	Joint pain, chronic headache	1
11	40	White	2	18.7	None	0.5

BMI = body mass index.
[a] In years, until surgery date.

operative time, length of hospital stay, and time from surgery to questionnaire response. An 8-question survey that consisted of multiple choice and open-ended questions was created for this study. The survey addressed patients' feelings about the removal of Essure implants and the surgery itself, family and/or partner support, and symptom improvement after surgery.

Patients were identified as meeting the inclusion criteria for this study by review of surgical records. These patients received an introductory letter with an explanation of the study and instructions for participation. Patients who chose to participate were mailed a paper version of the survey, which included a REDCap (Nashville, TN) online participation link [5]. Descriptive analysis was performed with Microsoft Excel (Redmond, WA).

Results

Based on a review of surgical records, 11 patients were identified who met the inclusion criteria. All patients invited to participate completed the survey (Table 1). The median age of the participants was 35 years (range, 25–44), and most of the women were Caucasian (n = 9; 81.8%). Median BMI was 24.7 kg/m^2 (range, 18.7–35), and median parity was 3 (range, 2–7). Of the 11 patients, 5 reported a history of chronic pelvic pain.

The median timeframe between removal of the Essure implant and administration of the survey was 5 months (range, 1–23). Patients reported symptoms after Essure placement for a median of 2 years (range, 0.5–9). The most common surgery performed for removal of Essure devices was bilateral salpingectomy (n = 7; 63.6%), followed by total laparoscopic hysterectomy and bilateral salpingectomy (n = 4; 36.4%). One patient initially had undergone bilateral salpingectomy, and then 7 months later, underwent a laparoscopic hysterectomy due to persistence of pelvic pain. Only 1 Essure removal was done hysteroscopically. Median operative time was 60 min (range, 35–140), and most of the patients were discharged home the same day (n = 9; 81.8 %).

Table 2 shows the results of the survey answered by the patients who underwent Essure removal. Most of the patients had pelvic pain symptoms (n = 10;90.9%), abnormal bleeding (n = 6; 54.5%), and pain during intercourse (n = 5; 45.4%) that were thought to be related to the Essure devices. Most patients reported physician agreement with the decision to remove the Essure implants (n = 8; 72.7%), as well as sufficient parental and partner support (n = 7; 63.6%) regarding their decision.

After surgery, most of the patients (n = 8; 72.72%) reported an improvement in all domains that were queried (pelvic pain, daily activities, sexual life, quality of life, healing, and recovery) (Fig. 1). However, 3 patients reported ongoing symptoms after surgery, and 2 reported worsening symptoms of pain and dyspareunia.

Discussion

In this case series, most patients experienced improvement of symptoms following surgical removal of Essure via salpingectomy and/or hysterectomy. This study differs from previous studies on this topic [6,7], because it surveyed patients' feelings during the postoperative period following surgery for symptoms that they believed to be related to the Essure device. Usually, satisfaction indexes after placing Essure are high, and patients are happy with their decision [6,7]. However, it is also well established that Essure placement can be associated with side effects after placement.

Pain was the most commonly reported symptom in our patient cohort. Pelvic pain may develop after hysteroscopic sterilization (incidence of 8.1%), with 50% of these cases